IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:	
Garret D. Cawthon	Before the Examiner Marina Lamm
Serial No. 10/626,069	
Filed July 24, 2003	Group Art Unit 1616
METHODS COMPOSITIONS AND SYSTEMS FOR THE PREVENTION AND TREATMENT OF DIAPER RASH	

DECLARATION OF GARRET D. CAWTHON UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Garret D. Cawthon, hereby declare that:

1. I am the inventor on the above-captioned patent application and am familiar with its content.

2. My degrees include a B.S. degree in Chemical Engineering from the University of Louisville, M.Eng. in Chemical Engineering with Honors from the University of Louisville, a Ph.D. in Chemical Engineering from The Ohio State University, and an Entrepreneurship M.B.A. with Distinction from the University of Louisville. I have significant experience in research relating to polymer engineering, including significant work for Dow Corning and Ashland Chemical, both of which are companies that manufacture and sell compounds that can be included in diaper rash treatment compositions described in the present application. Further

information relating to my education and experience in this field is provided in my *curriculum vitae*, a copy of which is attached hereto as Exhibit A.

3. I have carefully reviewed the outstanding Office Action in the present case, dated November 30, 2005, and the art references cited therein, together with the prior Office Actions dated June 16, 2005 and November 26, 2004. In particular, I have reviewed the assertions that the subject matter recited in the pending claims would have been obvious to a person of ordinary skill in the art over either Adams et al. or Gebhart in view of Moss and Mulder. I have also considered the current amendments to claims 39, 51, 58 and 59, and new claims 74-79 that are set forth in the document entitled "Response to Office Action" to which the present Declaration is attached and the Declarations of Dean Harper and Shishir Shah that are submitted herewith.

4. In the outstanding Office Action, the Examiner makes the following statement regarding my previously-submitted Declaration:

> The declaration under 37 CFR 1.132 filed 8/16/05 has been considered but is insufficient to overcome the rejections...because: the Applicant has not presented any experimental data in support of her [sic] opinion. Due to the absence of tests comparing Applicant's compositions with those of the closest prior art and apparent self-interest of the declarant, the declaration constitutes self-serving opinion testimony, which is entitled to little weight. (Office Action, Page 9) (emphasis added).

To address the underlined point in the above statement, the undersigned has now formulated compositions according to the formula set forth in Table 1 at Column 5 of the Mulder reference, which is considered to be the "closest prior art" of record based upon the statements made therein, and has completed extensive testing on the same and on multiple compositions described and claimed in the present application. As discussed further below, Applicant has determined that the composition described in Mulder does not have the properties described and claimed in the present application and therefore does not teach or suggest the invention claimed in the present application, as amended.

5. As is also discussed in the Harper Declaration, rheology is the science of flow and deformation behavior caused by external forces. Simple liquids, such as water and low molecular-

weight mineral oils, have what is called Newtonian behavior. This means that the liquids exhibit a constant viscosity independent of the level of shear rate applied. More complex systems are composed of liquid-liquid dispersions, liquid-solid dispersions, or emulsions. These systems are heterogeneous at a microscopic level although they look homogeneous to the naked eye. The heterogeneity helps create the non-Newtonian behavior. The major reason for this non-Newtonian behavior is due to particle/molecule interactions. Interactions with an emulsion's micelles can create similar behaviors. There are several other influences: molecular structure, particle shape/size/size distribution, temperature, pressure, time under shear. For example, decreasing the particle size can greatly increase the viscosity and particle interactions, and help generate non-Newtonian behavior. Using a higher melting point (i.e., more insoluble) mineral wax can create a similar effect. Producing an emulsion with smaller, finer micelles can generate more particle interactions.

6. Variables that can further influence the rheology include concentration, particle size, particle size distribution, adsorbed surface layers, shear rate, time, and particle charge. The predominant outcome of these particle-to-particle interactions in compositions encompassed by the present application is that the mixtures are shear-thinning, which means that the viscosity measured at rest (i.e., under no shear) is greater than the viscosity measured agitated/stirred (i.e., under shear). From a microscopic viewpoint, the particles can move past each other much easier the faster they are moving. When sprayed, a mixture experiences a shear rate several orders of magnitude greater than at rest; the resultant viscosity decreases asymptotically with increasing shear rate. In this regard, three formulations encompassed by the present invention were sent to an independent laboratory for rheological testing. The results of this testing, attached hereto as Exhibit B, establish that the three formulations (described as Formulations 1, 2 and 3 in Paragraph 13 below) are shear thinning compositions.

7. Another important feature inherent in many non-Newtonian systems is what is called a yield stress, or Bingham plastic behavior. Examples of systems exhibiting this feature are ketchup and mayonnaise. These materials do not flow out of the bottle until a specific shear stress is applied; the bottom of the ketchup bottle must be jolted to remove it, and it flows easily once in

motion. This behavior is greatly beneficial for spray-on treatments for diaper rash because it reduces run-off from the skin.

8. The rheology associated with spray applications is much more complex than that found with traditional ointments and lotions. In a spray actuator, the appropriate viscosity must not be too high or the atomization will be insufficient, which results in the material sputtering or streaming out of the actuator. Too low of viscosity is not a problem for atomization but it is a problem after the material is dispensed because it results in run-off of the composition from a skin treatment area. The fineness of the spray particles helps create a smoother, more even coating that also helps prevent run-off. It is also more cosmetically appealing. High shear rates are required to break the mixture apart into the fine droplets necessary for spraying. Mechanical action is exerted during the pumping action of a pump sprayer, or with the high pressure flow of material caused by elevated pressures used in propellant and bag-in-can systems described in the patent application. Specifically, this mechanical action can break the micelles of an emulsion, helping to dispense the hydrophobic ingredients onto the surface of the skin.

9. Within a typical spray container, there is relatively no shear on the liquid while it resides in the container unless the material is shaken. High shear rates are required in the actuator to separate the liquid into small droplets, and to propel the stationary liquid over a given distance. In fact, the difference in shear rates between the two locations of the spray container is about 10 orders of magnitude. Lastly, there is no shear on the material after it has been dispensed onto the skin.

10. Additional complexities must also be factored into the formulation: yield stress and viscoelastic (e.g., thixotropic) behaviors. The larger the yield stress the more difficult the liquid is to pump through the dip tube to the actuator, which must be counterbalanced by its improved run-off resistance. Thixotropic behavior is the time dependent thinning of the fluid; faster recovery of the "thickness" helps with run-off resistance although it accentuates brushmarks in paint applications. Further information regarding these and related rheological concepts is provided in the Declaration of Dean O. Harper submitted herewith.

11. The rheological properties of non-Newtonian systems are complex and a simple Brookfield viscosity measurement can not completely describe the rheology. There are many non-Newtonian behaviors: yield stress, shear thinning, thixotropic time dependency, etc. Specifically, two thixotropic samples having the same formulation can have different viscosities due to one having been stirred more recently. Since many of these materials act like elastic solids under some conditions and viscous liquids under others, they are viscoelastic materials. If the product should appear solid-like under "at rest" conditions, rheological testing should be carried out at low stress and over long periods of time to simulate this. If predicting the spraying of material for proper atomization, rheological tests should be carried out under similar shear rate and stress conditions.

12. The proper instrument selection and correct technique is critical for characterizing products at both low shear rates and high shear rates. Brookfield-type viscometers do not have accurately defined shear rates, limited shear rate range, only unidirectional shear is possible, and there is a need for temperature control. For the described formulations, a Brookfield viscometer has movement of liquid only at spindle and cannot measure viscoelastic behavior. A rheometer is required for testing under the higher stresses associated with spraying, and offers both unidirectional shear and rotational measurements. Either a rotational rheometer or a capillary rheometer can determine viscosity characteristics under high shear rates typically found during spraying.

13. In the performance testing described herein, multiple compositions were tested for sprayability and the degree of run-off resistance. The following compositions were tested:

Formulation #1 (detailed in the present application):

	Formulation #1
Zinc Oxide	25%
USP Lanolin	5%
USP Petrolatum	5%
Microcrystalline Wax	5%
Cod Liver Oil	10%
Light Mineral Oil	40%
Cyclomethicone	10%

Formulation #2 (detailed in the present application):

	Formulation #2
USP Lanolin	10%
USP Petrolatum	10%
Microcrystalline Wax	8%
Cod Liver Oil	10%
Light Mineral Oil	47%
Cyclomethicone	15%

Formulation #3 (detailed in the present application):

	Formulation #3
Calendula Extract	3%
Chamomile Extract	3%
Comfrey Extract	3%
Lanolin	5%
Beeswax	5%
Lavender Oil	1%
Geranium Oil	1%
Sunflower Seed Oil	54%
Cyclomethicone	25%

Formulation #4 (product encompassed by the pending claims):

	Formulation #4
Zinc Oxide	25%
USP Lanolin	2%
USP Petrolatum	3%
Microcrystalline Wax	2%
Vitamins A&D	0.3%
Light Mineral Oil	25.7%
Cyclomethicone	12%
Dimethicone	20%
Hexamethyldisiloxane	10%

Formulation #5 (product encompassed by the pending claims):

	Formulation #5
USP Lanolin	3%
USP Petrolatum	25%
Microcrystalline Wax	2%
Vitamins A&D	0.3%
Light Mineral Oil	29%
Cyclomethicone	10.7%
Dimethicone	20%
Hexamethyldisiloxane	10%

Formulation #6 (composition set forth in Table 1 at Column 5 of Mulder's US Patent 5,536,502):

Medicament	Weight Portion Ingredient (%)	
Carrier	Deionized Water	47.80
	Aloe Vera Gel	1.00
	Mineral Oil Gel	10.00
	Beeswax	1.00
	*** Carrier Subtotal	*59.80
Humectant	Glycerine 96%	*13.50
	Lanolin Oil	9.50
	Octyl Palmitate	5.00
	Isopropyl	2.00
Lanolate		
	*** Emollient Subtotal	*16.50
Keratolytic	Allantoin	0.50
	Urea	0.10
	*** Keratolytic Subtotal	*0.60
Odor-Reducing Agent	Hydroxyquinoline	*0.75
Preservative	Trisodium EDTA	0.05
	Methylparaben	0.30
	*** Preservative Subtotal	*0.35
Topical Protectant	Zinc Oxide	*2.00
Scenting Agent	Methyl Salicylate	*0.25
Emulsion Stabilizer	Sorbitan Sesquioleate	0.25
	Stearic Acid	3.00
	Lanolin Derivative Wax	0.30
	***Emulsion Stabilizer Subtotal	*3.55
Vitamin E	.alpha.-tocopherol	*1.00
Alkalizer	Sodium borate	*1.00
Pigment Wetting Agent	Isopropyl esters of fatty acids (e.g., Amerlate P from Amerchol)	*0.70
	Total	100.00

The Mulder composition was made by mixing ingredients together and heating to 70°C to ensure that all solids were liquefied. Mixing was performed throughout with a Ross high shear mixer.

14. One property that was tested was the sprayability of the respective formulations. The sprayability standard requires that the material can be atomized and dispensed in a spray form using a pump spray mechanism (i.e., without using propellant gases). Specific actuators can be used to spray compositions such as those claimed in the present application. Two examples include SeaquistPerfect's (www.seaqperf.com) EuroMist HV spray actuator and Calmar (www.calmar.com) Mark VI/VII systems. I used SeaquestPerfect's Eurogel spray actuators for the tests. The quantitative measures of the spray in the present study include:

- A reasonably sized (e.g., 2-12 square inches of) surface area covered when the actuator is a nominal distance (e.g., 2-6 inches) away from the surface.
- The coating should be even and in a typical circular pattern (with a diameter of 2-4 inches) that has a relatively even amount of material dispensed over the entire area.
- The amount required to be dispensed for an adult patient (i.e., 0.2-2.0 g) can typically be delivered in 1-to-6 pump sprays; additional pumps require more-than-desired time and effort.

15. Each of Formulation #1 to Formulation #5 passed the sprayability test; however, Formulation #6 (the Mulder formulation) did not. The Mulder composition had a consistency that resembled pancake batter at 50°C and a thick paste at room temperature. The liquid was sprayable at 50°C but not at room temperature, and thereby failed the sprayability test. The consistency of the formula is typical with one having such high levels of "thick" ingredients: 10% Mineral Oil Gel, 13.50% Glycerine, and 9.50% Lanolin Oil. An emulsion base further increases the viscosity.

16. Run-off resistance can be measured in a variety of ways but a good protocol can be found in the Healy et al. patent (US 6,949,249). The method consists of the following steps:

- Place the spray nozzle 2 inches away from a piece of Formica® plastic laminate.
- Dispense a total of 0.39 ml using two full pumps of the actuator.
- Rotate the piece of plastic laminate into a vertical position so that the plane of the circle is perpendicular to the horizontal workforce.
- Draw a line 4 inches below the bottom of the circle and parallel to the horizontal workforce.

- Measure the time its takes for any material to flow past the marked line. Compositions with acceptable run-off resistance take longer than 5 minutes to pass the line. Longer times are preferred.

All of the samples (formulations 1-6) satisfied the run-off resistance test. Indeed, all six of these formulations had run-off resistance times of greater than 1 hour. It is important to keep in mind, however, that formulation 6 failed the spray test at room temperature as described in paragraph 15. Formulation 6 was so thick and paste-like at room temperature, it is not surprising that it passed the run-off test at room temperature. This result is moot, however, given the failure of formulation 6 in the spray test. While formulation 6 was sprayable at 50°C, it would be undesirable to spray hot liquid onto the skin.

17. In addition to the above, the nonobviousness of the claimed invention is supported by the fact that multiple embodiments of the invention (see, for example, formulations 4 and 5 above) have been recognized by experts in the relevant field as being a significant advance over the prior art. In particular, the present invention has been recognized by the medical community for its unique technology and performance. For example, the products I have developed and marketed that embody the claimed invention (available for purchase at www.touchlesscare.com) recently won the top vote award at the MedAssets' New Technology Fair, at which 47 preselected high-tech healthcare companies presented their new products. MedAssets is the third largest Group Purchasing Organization in the US, and has contractual relationships with about one-fourth of all US hospitals. The judges were composed of technical specialists in the various disciplines, including skin and wound care specialists. The grading criteria (based on a 4.00 scale) used by the judges were as follows, and the scores of the inventive compositions are set forth in parentheses:

Vendor's technology...

- is new and can be considered "breakthrough" technology (4.00).
- will have a significant impact on improving patient care (3.93).
- will have a significant impact on improving labor efficiency (3.91).
- will have a significant impact on improving cost efficiency (3.84).
- will benefit the MedAssets' contract portfolio (3.81).

Overall Score: 3.90 (#1 out of 47 companies)

Attached hereto as Exhibit C is a copy of the letter reporting the above-described result and detailing this information. In addition, my company and its spray-on products that embody the invention described and claimed in the present application were recently selected as a finalist for the Henry Vogt award for excellence in product innovation.

18. I further declare that all statements made herein are of my own knowledge, are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

5/24/06
Date

Garret D. Cawthon, Ph.D.

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EXHIBIT A

GARRET D. CAWTHON

1215 Summit Avenue
Louisville, KY 40204
(502) 479-7798

EDUCATION: University of Louisville, Louisville, KY
Entrepreneurship M.B.A. ***with Distinction*** (1994)

The Ohio State University, Columbus, OH
Ph.D., Chemical Engineering (1988)
Thesis: Optimization of Semibatch Copolymerization Reactions

University of Louisville, Louisville, KY
M.Eng., Chemical Engineering ***with Honors*** (1984)
B.S., Chemical Engineering (1983)

EXPERIENCE: **Touchless Care Concepts, LLC**, Louisville, KY
Chief Executive Officer (1/99-Present)
Responsible for the development of technology, commercialization of products, establishment of corporate partnerships and financing, and implementation of the company's business plan.

Key Accomplishments:
- Submitted patent applications and began marketing campaign.
- Developed e-commerce web site for on-line ordering.

University of Louisville, Louisville, KY
Adjunct Professor, Chemical Engineering Department (8/02-Present)
Taught the class to (non-thesis option) graduate students in which they develop research proposals and business plans.

University of Louisville, Louisville, KY
Assistant Visiting Professor, School of Business and Public Administration (1/00-5/00)
Taught Principles of Operations Management to undergraduate business students.

Advanced Biorefining Corporation, Louisville, KY
Chief Executive Officer (2/98-12/00)
Prepared and promoted business plan for manufacturing three products from agricultural wastes, such as corn cobs and oat hulls. Optimized technology through lab and pilot scale experimentation. Consulted to other various companies about marketing and technical issues for agriculturally-derived products.

Key Accomplishment:
- Solicited $300,000 in investment capital

GARRET D. CAWTHON

1215 Summit Avenue
Louisville, KY 40204
(502) 479-7798

University of Arkansas, Fayetteville, AR
Assistant Visiting Professor, Operations Management (06/95-5/98)
Taught three courses to graduate-level students: Economic Decision Theory, Public Financial Administration, and Principles of Operations Research.

Key Accomplishment:
- Received letter of commendation for excellent teaching from students' performance reviews.

Great Lakes Chemical Corporation, Memphis, TN
Senior Process Engineer (11/94-1/98)
Prepared financial/technical analyses for over two dozen projects, including the largest internal investment within GLCC. Led a team of scientists/engineers in new technology development to decrease the manufacturing costs of a key intermediate by 35%.

Key Accomplishment:
- Commercialized several lab-based products by leading the process design, equipment selection, construction, and start-up activities.

University of Louisville, Louisville, KY
Associate Adjunct Professor, Chemical & Environmental Engineering (9/92-6/94)
Taught two advanced courses in the Chemical Engineering department. Consulted with high-tech firms as a Professional Engineer while completing my M.B.A. degree.

Key Accomplishment:
- Assisted in the development of a business plan for procuring $4,000,000 in start-up capital.
- Completed a strategic management analysis for a small, but rapidly growing medical device manufacturer/distributor.

Ministry of International Trade & Industry, Japan
Engineering Specialist (1/92-6/92)
Completed 6-month project for developing pervaporation membrane systems used to separate trace organics from industrial wastewaters.

Key Accomplishment:
- Improved membrane performance by 40% using novel surface treatment techniques.

GARRET D. CAWTHON

1215 Summit Avenue
Louisville, KY 40204
(502) 479-7798

Dow Corning Corporation, Carrollton, Ky
Project Engineer (4/90-9/91)
Provided technical leadership to the start-up of an $8,000,000 silicone manufacturing facility. Directed installation and initial operation of safety systems, storage tanks, and processing equipment. Instructed engineers and technicians in safe work practices. Left to pursue M.B.A. full-time.

Key Accomplishments:
- Achieved safe process operation and production timetable through four months of shift work.
- Debugged the computer control system and optimized process throughput to meet designed performance levels.

Dow Corning Corporation, Midland, MI
Project Engineer (11/87-3/90)
Installed and operated a $400,000 automated pilot plant used to make silicon-based polymer additives. Led a three engineer/four technician team in new product development. Performed laboratory experiments to optimize manufacturing performance.

Key Accomplishments:
- Supplied development-level quantities of new products for customer evaluation studies.
- Awarded U.S. patent for a high-purity ceramic coating used to protect electronic circuitry.
- Coordinated regulatory compliance activities for three production facilities.

Ashland Chemical Corporation, Columbus, OH
Engineering Consultant (6/86-3/87)
Utilized my Ph.D. research to improve product/process performance of polyester and phenol-formaldehyde resins. Coordinated pilot plant and analytical laboratory activities for computer modeling studies.

Key Accomplishment:
- Proposed new manufacturing procedures to lower batch production time by 12%.

EXHIBIT B

Applications Report on Rheological Measurements of Rash Relief Sprays

Prepared For: Garret. D Cawthon PhD

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2006-03-01

Introduction

The rheological analysis of samples is a fundamental part of developing spray behaviour of fluids and ointment. Whilst they still have their place, the use of basic desktop viscometers is being found to often give insufficient results. These simple devices do not match the versatility of modern rheometers, nor can they ensure that a new product will be suitable for use. A rheometer can actually measure sample properties at extremely low shear rates, as in sedimentation, or the high shear rates seen in pumping, mixing and application.

The rheometer not only measures the viscosity of the product at room temperture, but can also be used to evaluate the viscosity during a programmed temperature profile. Results are accurate with minimal time spent testing, as a pre-programmed analysis may be started and left to run unattended, or even overnight.

A Synopsis of Rotational Rheology

Rotational rheometers can accommodate many different measuring systems, although the most common are the cone and plate, the parallel plates, the coaxial cylinders and the torsional fixtures. In the case of the cone and plate or parallel plates, the sample is loaded onto a temperature controlled flat lower plate and an upper cone or flat plate is lowered onto the sample squeezing it into a defined space. After trimming away excess sample, the upper measuring system is then either sheared in one direction (viscometry) or oscillated rotationally (oscillation, as shown in Figure 1 below).

Viscometry can be used to investigate the yield stress, ie the stress required to initiate sample flow, simulate a shearing process, measure shear stability or analyse how viscosity changes with temperature. Oscillation tests usually investigate the viscoelastic structure of a sample without breaking it down. Initially an amplitude sweep is run to determine how large an oscillation the sample can withstand before the structure breaks down, this is know as the linear viscoelastic region. Once the linear viscoelastic region has been determined, a frequency sweep, time sweep or temperature sweep may be operformed to investigate how the viscoelastic structure and viscosity changes under dynamic conditions. More information is given on these techniques and creep and relaxation tests in the appendix: An Introduction to Rheology.

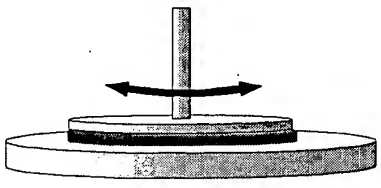


Figure 1 – Rotational oscillation of a sample loaded between a cone and plate.

Sample Testing

Three samples were submitted for testing.
Rash Relief, a petrolatum/lamolin semi solid within a cyclomethicone/mineral oil fluid phase
Rash Relief with Zinc Oxide, 25% ZnO dispersion within a cyclomethicone/mineral oil fluid phase
3C Skin Therapy, Herbal extracts of Calendula, Chamomile, and Comfray with a cyclomethicone/sunflower seed oil phase

Method

Shear Rate Ramp

Temperature 25C
Shear Rate Range 10 -100,000 1/s

Oscillation frequency sweep

Amplitude 0.001
Frequency: 0.1 – 10 Hz
Temperature 25C

Preshear/ Dynamic Time Sweep
Presshear 60 sec at 100 1/s
Dynamic Frequency 1 Hz
Amplitude .001

Results

Purpose of Rheological Measurements:
Three samples of ointments were tested. They are Rash Relief, Rash Relief with ZnO, and Skin Therapy. These samples are sprayed onto the skin. When delivered from a spray bottle, the ointments should spread uniformly onto the skin and need to stay in place. Controlling this behavior are the drop size and viscosity of the ointment. If the ointment jets as a continuous stream from the spray bottle, it will not spread uniformly. Also if it is too low in viscosity it will not stay on the affected area of the skin.

Three tests are performed to identify the relevant rheology relating to spray behavior ability of the ointment to stay in place.

High Shear Rate Measurements:
Spraying is a high shear rate process. The rates will depend upon the size of the orifice and the volume flow rate of the liquid. The shear rates in the range of 10^4-10^5 1/s were reported for these samples. Viscosities of the samples were determined in this range of shear rates.
Figure 1 compares these flow curves for these three samples. Rash Relief with ZnO has a slightly higher viscosity than Rash Relief; where as Skin Therapy is much lower than the other two samples.

Figure 1

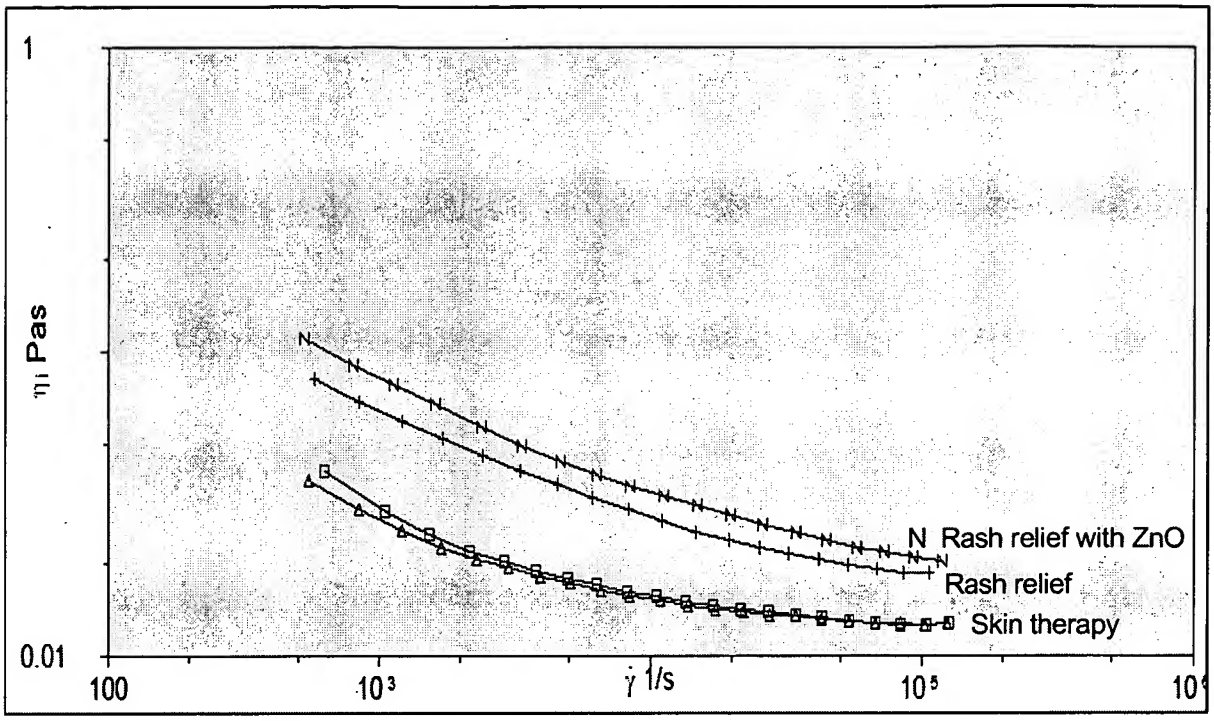


Table 1 lists the viscosities at 10^5 1/s. The Skin Therapy viscosity is the average of two measurements. These values are 0.01262 and 0.01255 Pas. The precision of this measurement is 0.3%.

Table 1

Ointment's Viscosities at High Shear Rates

Sample	Viscosity, Pas (at Shear Rate at 10^5, 1/s)
Rash Relief	0.02038
Rash Relief with ZnO	0.02103
Skin Therapy	0.01258

Oscillatory (Dynamic) Measurements:

Spray atomization depends upon the ability of the jet to break up into very small droplets. Typically, there will be a distribution of drop sizes. Furthermore the spray will fan out creating a conical shape pattern. The characteristics of spray behavior is controlled by the rheology to the jet exiting from the nozzle, surface tension, and the shape and volume flow rate, i.e., shear rate of the fluid delivered from the spray bottle.

In order to identify the rheology that controls the spray behavior of these samples their viscoelastic properties were determined. Elasticity has a major effect on the spray characteristics. Fluids that are most elastic will tend to form a jet stream and break up into large drops and form a narrow spray pattern.
As seen for Figure 2, which compares the frequency sweeps of these three samples, it is apparent that the elasticity, as measured by the storage modulus, G', is frequency dependent. However, frequency is a measure of the time response to the deformation rate. The Deborah number, defined by the ratio of the relaxation time to the shear rate is invoked. For a jet sprayed at a shear rate of about 10^5 1/s. corresponds to a frequency in shear of 10^5 radians/s. One complication, is

that kinematics of jetting is an extensional mode of deformation. It is known that some fluids will show and increase in viscosity with increasing extension rate, but in shear will show a decrease. In order to use shear rheology to predict spray behavior it is necessary to identify want is controlling. From earlier work it has been found that the longest relaxation times, measured in shear relate the spray behavior. It is for this reason that the Table 2 lists the complex viscosities and storage moduli at 0.1 Hz. These data correspond to the longest relaxation time that was measured.

Figure 2
Composite Frequency Sweeps

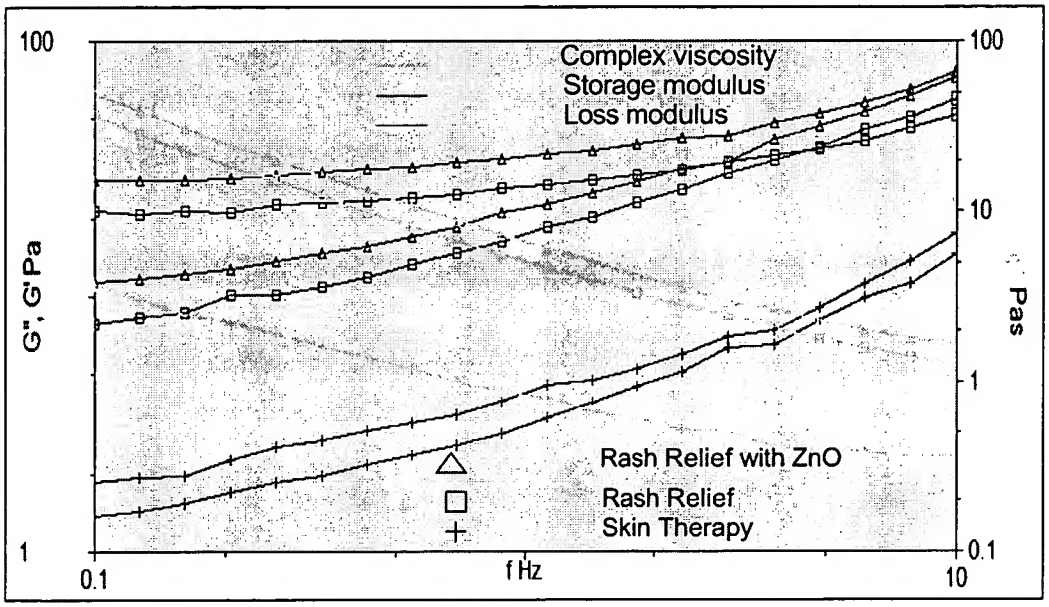


Table 2
Frequency Sweep Data at 0.1 Hz

Sample	Complex Visciosity,Pas	Storage Modulus, Pa
Rash Relief	36.53	21.61
Rash Relief with ZnO	48.51	28.33
Skin Therapy	3.68	1.87

The Rash Relief with the ZnO has the highest storage modulus and is predicted to produce the largest drop sizes. Conversely, the Skin Therapy will produce the smallest drops.

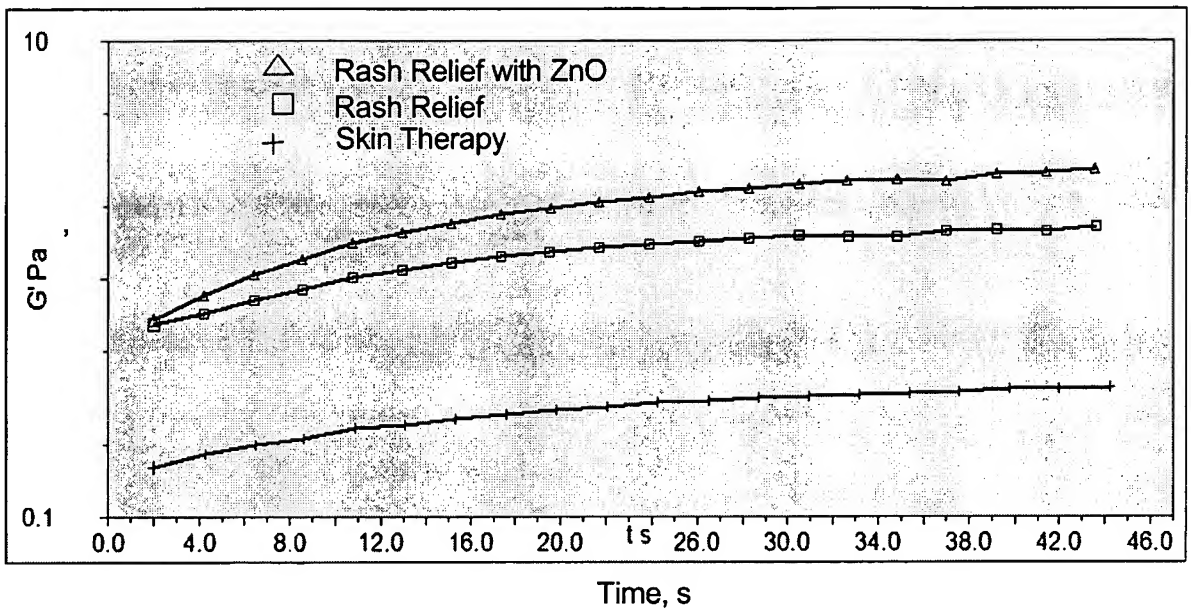
Oscillatory Time Sweep

For the ointments to stay in place once sprayed onto the skin, the rate at which the ointment builds structure is a measure its ability to not flow and drip off the skin.

The test that was performed to identify this ability stay on the skin is a "preshear shear oscillatory time sweep" Preshear will break the structure, as it does when the sample is sprayed, and the oscillatory time sweep will determine the rate of structure recover shortly after the ointment makes contact with the skin
Figure 3, show a comparison of these test results. The storage modulus is a measure of structural recovery. The Rash relief with Zone shows the fastest rate of structural recovery. Although, the Skin Therapy has the lowest overall storage module its rate of recovery is the same as the Rash Relief.

Figure 3

Structure Building following Preshear



Conclusion

All of the spray samples were able to be tested simply using the Bohlin rheometer and the tesing was all carried out using only one measuring system: the parallel plate 40 mm. The rheometer was able to gain information regarding the storage stability, resistance to pumping, thickness perception when stationary and when applied from the viscometry. The oscillation tests confirmed the storage stability, as well as showing the ability of the spray to stay in situ after application.

When set-up, the rheometer would provide quick, absolute and reproducible measurements, with no technician intervention once the test had been started. The rheometer would provide a non-subjective method, giving a firm foundation for product formulation or quality control.

Some of the 'user benefits' of the rheometer that were identified from the testing included:

Air Bearing Design: Superior sintered graphite bearing with absolute position sensing and active torque mapping over 512 points. This allows accurate measurement of low viscosity samples without instrument friction interfering.

Motor: High torque, low inertia, induced magnetic field motor, making for great oscillatory measurements and less frequent instrument recalibration.

Position/shear rate controller: Bohlin Rotonetic™ ultra high frequency digital control system. This allows true controlled stress, strain and shear rate testing.

Rapid Temperature Control: Peltier –10 to 180°C computer controlled (upper limit with hot water in bottle)

Free Rheology Support – Well trained rheologists available for advice and help by telephone and email

Free Technical Support – technical support team available 08:30 to 17:30 to advise on any instrument or test set-up problems.

Wide Range of Accessories Available – to allow flexibility for future development.

Software Features

Context sensitive help system – one click help from any page in the software
User definable formats for results exporting
Automatic saving throughout the test to save data in the event of a power failure
Post test automation and results reporting
Access to advanced method set-up and sampling in all test modes.
JobStream sequencer – allows automatic sequencing of multiple tests, saving, and data processing

EXHIBIT C

December 8, 2005

Garrett Cawthon
Touchless Care Concepts, LLC
PO Box 6626
Louisville, KY 40206

MedAssets Supply Chain Systems

MedAssets Supply Chain Systems | 3221 McKelvey Rd., Suite 301
Bridgeton, MO 63044
Tel: 314.291.2920
Fax: 314.770.7299
www.medassets.com

Dear Garrett,

Thank you for participating in the 2005 Technology and Innovation Forum hosted by MedAssets Supply Chain Systems. This event was viewed as a great success by MedAssets and the Advisory Committee members of MedAssets Supply Chain Systems which attended.

Based on the feedback which MedAssets Supply Chain Systems received from its Advisory Committee, your company has been selected to advance to the next step in our contract review process. Please contact John Julian at (314) 291-2920 who is the designated contract manager for your product lines. In some cases, the committee has asked that additional evaluations be completed prior to sending a formal Request for Proposal (RFP).

Again, thank you for your participation, and we look forward to further discussions with your company.

Sincerely,

Joseph Dysko
Executive Director
Engineering and Capital Resource Group
Materials Management Division

cc: Mark Miriani, MedAssets Supply Chain Systems
Frank Gillespie, MedAssets Supply Chain Systems

Touchless Care Concepts, LLC Ranking

Booth 34	Touchless Care Concepts, LLC	
Question 1	Breakthrough Technology	4.00
Question 2	Improving Patient Care	3.93
Question 3	Improving Labor Efficiency	3.91
Question 4	Improving Cost Efficiency	3.84
Question 5	Benefit MedAssets Portfolio	3.81
	Overall Score	3.90
Rank		1 of 47

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:	
Garret D. Cawthon	Before the Examiner Marina Lamm
Serial No. 10/626,069	
Filed July 24, 2003	Group Art Unit 1616
METHODS COMPOSITIONS AND SYSTEMS FOR THE PREVENTION AND TREATMENT OF DIAPER RASH	

DECLARATION OF SHISHIR SHAH UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Shishir Shah hereby declare that:

1. I have studied and I am familiar with the content of the above-captioned patent application.

2. My degrees include a B.S. degree in Aeronautical Engineering with Dean's List Honors from Rensselaer Polytechnic Institute, a Doctorate in Osteopathy with Honors from Midwestern University/CCOM .. I am board certified by both the American Board of Family Practice (ABFP) and the American Academy of Wound Management (AAWM). In addition to my significant experience in research relating to wound and skin care, I was also the CEO for Spray Technology Inc., the second largest commercial spray equipment retail and repair center in Arizona. This role gave me detailed knowledge of the issues associated with spraying mixtures.

Further information relating to my education and experience in this field is provided in my *curriculum vitae*, a copy of which is attached hereto as Exhibit A.

3. I have carefully reviewed the outstanding Office Action in the present case, dated November 30, 2005, and the art references cited therein, together with the prior Office Actions dated June 16, 2005 and November 26, 2004. In particular, I have reviewed the assertions that the subject matter recited in the pending claims would have been obvious to a person of ordinary skill in the art over either Adams et al. or Gebhart in view of Moss and Mulder. I have also considered the current amendments to claims 39, 51, 58 and 59, and new claims 74-79 that are set forth in the document entitled "Response to Office Action" to which the present Declaration is attached and the Declarations of Dean Harper and Garret Cawthon that are submitted herewith.

4. Upon entry of the amendments referenced above, the pending claims are directed to methods for spray delivery of diaper rash treatment compositions to a skin treatment area without the use of propellant gases (i.e., using non-aerosol delivery systems). While the use of aerosol formulations is encompassed by some of the more general concepts and aspects of the present invention, the distinctions between aerosol and non-aerosol aspects of the invention are significant. The amendments limiting the scope of the pending claims to non-aerosol technology further distinguish the invention claimed in this application, as amended, from the prior art. In particular, I believe and submit that the concept of spraying a composition using propellant gas-based aerosol technology is significantly different than spraying a viscous composition using non-aerosol atomizing spray mechanisms. Because both the Adams et al. reference and the Gebhart et al. reference describe sprayable compositions of only the aerosol type (i.e., spray mechanisms using propellant gases), those references cannot properly be found to be suggestive of methods and compositions encompassed by the present application which do not use propellant gases.

5. For the reasons set forth herein, I believe: (1) that a person of ordinary skill in the art would not have been motivated to modify the teachings of the cited references in a manner that would be necessary to arrive at the presently claimed invention, (2) that the present invention proceeds contrary to accepted wisdom that existed at the time the application was filed,

(3) that a person of ordinary skill in the art at the time of the invention would not have modified a low viscosity drug-delivery composition by adding high viscosity barrier-type ingredients in amounts necessary to provide a composition having the physical properties described and claimed in the present application because he or she would have expected the operability (i.e., sprayability) of the spray system to be degraded to a point where the modification would not be desirable, and he or she therefore would have had no reasonable expectation of success, (4) that a person of ordinary skill in the art at the time of the application would not have modified a highly viscous, hydrophobic barrier composition by adding viscosity-reducing or hydrophobicity-reducing ingredients at a level necessary to provide a composition suitable for passage through an atomizing spray dispenser without the use of propellant gases, as described and claimed in the present application, because he or she would have expected the operability (i.e., barrier functionality) of the barrier composition to be degraded to a point where the modification would not be desirable, and he or she therefore would have had no reasonable expectation of success, and (5) that the claimed invention therefore would not have been obvious over the disclosures in the references cited in the outstanding Office Action.

6. In determining what a person of ordinary skill in the art would be motivated to do upon consideration of the cited art, it is imperative to consider that such a skilled person would understand the difference between oily, pasty, hydrophobic barrier-type ingredients and other types of ingredients that would reduce the barrier functionality of a composition. It is therefore inappropriate to focus solely upon the question of whether a given ingredient is of the type that a person of ordinary skill in the art would consider including in a diaper rash treatment composition, without regard to the physical properties of the ingredient or the desired effect of the ingredient on the physical properties of the composition. A person of ordinary skill in the art would have found no motivation in the prior art to deliver a barrier-type diaper rash composition via an atomizing spray dispenser. It is important to keep in mind that the pending claims recite compositions having specific physical properties, namely, "a viscosity sufficiently low to allow the composition to be atomized upon passage through the atomizing spray dispenser and sufficiently high that the coating does not run off of the skin treatment area." (emphasis added).

7. Simply combining ingredients that are considered to be acceptable for inclusion in a diaper rash treatment composition is not sufficient to arrive at the present invention as recited in the pending claims, and the identification of all known ingredients that might be suitable for inclusion in a diaper rash composition would not have motivated or enabled a person of ordinary skill in the art to practice the present invention. Indeed, based upon my experience and knowledge in this field, I submit that a person of ordinary skill in the art at the time of the present application would not have believed that a composition could have been formulated that is capable of BOTH being applied to a skin treatment area via an atomizing spray dispenser without using propellant gases AND providing a suitable barrier functionality for the treatment of diaper rash. These characteristics are at odds with one another, and a person of ordinary skill in the art would not have believed that such a formulation could be developed. There is certainly no description or suggestion in the cited references of a composition that has both of these capabilities. Absent the motivation provided by the present invention, a person of ordinary skill in the art would not have combined ingredients from the respective references in a manner that would be necessary to practice the present invention. Indeed, based upon my significant experience in this field, I believe that a person of ordinary skill in the art would not find any motivation to combine ingredients in a suitable manner to provide a composition that has physical properties that "allow the composition to be atomized upon passage through the atomizing spray dispenser [without a propellant gas]" and with a viscosity "sufficiently high that the coating does not run off of the skin treatment area." There is simply no teaching or suggestion of a composition in the cited references that has the combination of physical properties discussed herein, nor is there any teaching of how such a composition could be made.

8. The present invention proceeds contrary to the accepted wisdom that existed at the time the application was filed. To accurately understand the suggestive effect of the cited references, and to fully appreciate what the cited references would suggest to one skilled in the art at the time of the invention, it is important to consider the art as a whole at the time the invention was made, including trends and beliefs in the field of diaper rash treatment and the perspective of a person skilled in the art. A person of ordinary skill in the art at the time of the present invention

would have understood that all diaper rash treatment products fall into one or both of the following two categories: "protective barrier" compositions and "active agent delivery" compositions. Of course, a given product could belong in both categories, i.e., a protective barrier composition could also include one or more active agents. However, one important distinction between these two categories of diaper rash treatment products is the following: while active agent delivery compositions could take a wide variety of physical forms (i.e., aqueous liquids, emulsions, creams, ointments, pastes, powders or other solids), the physical form of protective barrier compositions was and is relatively uniform: a highly viscous, typically hydrophobic, paste, ointment or cream. Such highly viscous compositions were believed to be necessary to provide a suitable protective barrier product.

9. Significant efforts have been made in the prior art, and significant resources have been devoted to efforts to identify the precise cause or causes of diaper rash, with the belief that this would enable the development of formulations that include active ingredients selected to address the cause more directly. Even in view of significant efforts to identify the specific cause of diaper rash, it was generally believed at the time the present application was filed, and is generally believed at this time, that the most important feature of a diaper rash treatment composition is its ability to provide a physical, non-soluble barrier between urine and/or feces and the underlying skin. As stated at page 3 of the present application:

> Because the suspected agents of diaper rash ... all possess diverse properties and require varied therapies, conventional methods of treatment for diaper dermatitis have been directed toward a straightforward attempt to minimize the contact of the skin with the feces or urine present in a soiled diaper. An artificial barrier is usually provided between the skin and the body waste to accomplish this... [Because] the exact components of urine or feces which act as factors or cofactors contributing to diaper dermatitis have never been precisely identified, the most effective method of treating diaper rash to date has been the artificial barrier.

10. In keeping with the trend of providing an artificial barrier in conventional treatments of diaper rash, a wide variety of highly viscous pastes, ointments and creams have been developed to be applied to skin in an effort to provide a suitable barrier to prevent skin contact

with urine and/or fecal matter. Because urine is an aqueous liquid, and fecal matter sometimes also has a high water content, it has been long understood and widely accepted that, to be effective, the paste, ointment or cream should be formulated as a highly viscous, hydrophobic preparation.

11. In view of this background, it is apparent that the present invention proceeds contrary to the accepted wisdom that existed at the time the application was filed. A person of ordinary skill in the art at the time of the present invention would have understood the limitations on the physical characteristics of ingredients in a barrier composition, and would not have been motivated to add ingredients into a barrier formulation that would reduce the viscosity or hydrophobicity thereof, much less try to formulate a barrier composition that could be passed through an atomizing spray delivery mechanism without the use of propellant gases. Similarly, a person of ordinary skill in the art would have had no motivation to pluck ingredients from a "protective barrier" composition for inclusion in a liquid "active agent delivery" composition.

12. A person of ordinary skill in the art at the time of the application would not have modified a low viscosity, non-aerosol, sprayable composition by adding high viscosity barrier-type ingredients at a level necessary to provide a composition having the physical properties described and claimed in the present application because he or she would have expected the operability (i.e., sprayability) of the spray system to be degraded to a point where the modification would not be desirable. He or she therefore would have had no reasonable expectation of success, and would not have been motivated to even attempt to make such modifications. Similarly, but from a different perspective, a person of ordinary skill in the art at the time of the application would not have modified a highly viscous, hydrophobic barrier composition by adding viscosity-reducing or hydrophobicity-reducing ingredients in amounts necessary to make a composition suitable for passage through an atomizing spray dispenser without using propellant gases, as described and claimed in the present application, he or she would have expected the operability (i.e., barrier functionality) of the barrier system to be degraded to a point where the modification would not be desirable. He or she therefore would have had no reasonable expectation of success, and would not have been motivated to even attempt to make such modifications. I believe that the prior art is devoid of any information suggesting that the combination of properties recited in the pending

claims would be achievable in a composition as recited in the pending claims, as amended. Indeed, based upon my experience and knowledge in this field, I believe that a person of ordinary skill in the art at the time of this application would not have expected any composition having a viscosity "sufficiently high that the coating does not run off of the skin treatment area" as recited in the claims, as amended, also to be suitable for delivery through an atomizing spray dispenser without using propellant gases, as also recited in the pending claims, as amended.

13. Reference is made in the Action to the Mulder patent in support of each of the claim rejections. With regard to Mulder, I believe that this reference is nonanalogous art. I am aware of the rule in the MPEP that, "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." (MPEP Section 2141.01(a)). Mulder cannot be relied upon as a basis for rejection of the pending claims, as amended, because it does not satisfy either of these two requirements.

14. Mulder is not in the field of applicant's endeavor. As stated at page 1 of the present application, "The present invention relates to methods, compositions and systems for the prevention and treatment of diaper rash." In contrast, Mulder states at Column 1, lines 7-9 that, "The present invention pertains to the field of topical ointments and, more particularly, to products that are used for the treatment of superficial lesions including skin tears." It is important to recognize that the field of endeavor involving treating skin tear wounds is significantly different than the field of endeavor involving treatment and prevention of diaper rash. A person of ordinary skill in the field of skin tear wounds would understand the importance of giving careful attention to cleaning any and all debris and infectious agents from the wound, applying medicines to the wound, keeping the wound clean, and ensuring that an unrestricted amount of oxygen is able to reach the wound to allow proper healing. With respect to the latter, a person of ordinary skill in the field of skin tear treatment would readily understand that a barrier-type composition such as those discussed in the present application, should never be applied over a skin tear wound. Numerous studies have shown that the proper healing of skin-breaking wounds is prevented by moisture barrier-type, or "occlusive" products, which suppress recovery and reduce the epidermal

proliferative response to the wound, while semipermeable, or "breathable," materials do not slow recovery and allow for normal cellular respiration. Thus, a barrier-type composition, or "occlusive product," as described and claimed in the present application simply should not be used in the field of skin tear wound care. In contrast, the field of diaper rash treatment, as discussed in detail herein, involves the placement of a robust and impermeable (non-breathable) barrier over an area of skin having, or at risk of experiencing, diaper rash. A barrier composition of this type would be totally unsuitable for placement on an open wound. Thus, barrier-type diaper rash treatment compositions should never be considered desirable for use in connection with a skin tear, and the two are properly considered different fields of endeavor.

15. Mulder is also not reasonably pertinent to the particular problem with which the inventor was concerned. In the development of the present invention, the particular problem with which Dr. Cawthon was concerned was that:

> products currently available for the treatment of diaper rash...are very viscous and messy to administer to the skin. Such products require that the person applying the product spread the product by rubbing the same into or over the skin. While this requirement is typically acceptable in the case of a parent applying the product to the skin of an infant child, it is a drawback where a caregiver is in charge of providing such a treatment to multiple persons, especially multiple incontinent adults. The application of the product is messy and awkward because the product is difficult to wash off of ones hand due to its oily, hydrophobic nature. Additionally, the caregiver must first use one set of gloves to clean the patient, and then use another set of gloves to apply the ointment or lotion. This results in wasted time and resources.

(Specification, Page 5, lines 3-13). Mulder is not reasonably pertinent to this problem relating to the mess and inefficiency of applying an oily, hydrophobic ointment to a skin treatment area. Rather, Mulder is focused upon addressing the "need for a non-irritating, topical ointment or medicament that is specifically designed to promote the reepithelialization of skin tears." (Mulder, Column 2, lines 18-20). This is not reasonably pertinent to the problem with which Dr. Cawthon was concerned because a product capable of promoting the reepithelialization of skin tears would not be pertinent to the problem of the mess and inefficiency of applying an oily, hydrophobic

diaper rash ointment to a skin treatment area. Furthermore, an oily, hydrophobic barrier-type diaper rash composition should never be used for treating skin tears, as discussed above, because a barrier composition would cause a significant impediment to wound healing. Indeed, the compositions described by Mulder are designed around the concept of washing/flushing the wound site, and thus only a small proportion of the composition applied to the wound would even remain after the flushing was completed. This is a fundamentally different purpose than the purpose of a barrier-type diaper rash composition, which functions optimally by being retained on the skin in its entirety. Thus, the properties that would be desirable in the respective types of compositions are significantly different. As such, Mulder is nonanalogous art because it is not in the field of applicant's endeavor or reasonably pertinent to the particular problem with which the inventor was concerned.

16. In summary, I submit that no reference of record in this case would be understood by a person of ordinary skill in the art to provide any teaching, suggestion or motivation to modify their teachings in a manner that would lead to the present invention. A person of ordinary skill in the art would find no motivation in these references to use a highly viscous paste, ointment or cream, or the ingredients thereof, in a spray system. A person of ordinary skill in the art would not have modified a highly viscous paste, ointment or cream protective barrier formulation to make it sprayable, and would not have selected ingredients thereof for inclusion in a spray-on diaper rash composition. Similarly, but from another perspective, a person of ordinary skill in the art would not have modified a low viscosity, sprayable composition by adding high viscosity barrier-type ingredients at a level necessary to provide a barrier-type composition, and would not have selected ingredients thereof for inclusion in a barrier-type ointment.

17. Many of the same principles set forth above concerning the asserted Adams/Mulder/Moss combination apply equally well to the combination of Gebhart et al./Mulder/Moss asserted in the outstanding Action. Gebhardt et al., like Adams et al. discussed above, describes "aerosol compositions for the treatment of skin irritations such as diaper rash." The formulations described by Gebhart et al., like those described by Adams et al., do not provide moisture barrier protection. The undersigned therefore submits that the cited references do not

teach or suggest a method as recited in the subject claims, and would not motivate a person of ordinary skill in the art to modify the references to arrive at the present invention.

18. The additional references cited in the outstanding Action, Boussouira et al. (US 6,103,247) and Neubourg (WO 99/08649 as translated by US 6,423,323), are cited as disclosing the inclusion of specific ingredients in a diaper rash treatment composition. For example, Boussouira et al. is cited in the Action as teaching the use of transparent zinc oxide having an average diameter of 1-500 nm in cosmetic compositions because of its aesthetic appeal, and Neubourg is cited as teaching the use of calendula and chamomile extracts in topical diaper rash treatment compositions. However, these references also fail to satisfy the missing teachings or suggestions in the primary references that are discussed above, and these references therefore cannot be combined with the other references to form a proper rejection of claims.

19. I further declare that all statements made herein are of my own knowledge, are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

5/22/04
Date

Shishir Shah, D. O.

KD_IM-689921_1.DOC

EXHIBIT A

SHISHIR V. SHAH D.O.
15029 N Thompson Pk #B111-478
Scottsdale, Arizona 85260

Phone: 623-512-3410
fax: 413-487-9245
email:svshah70@yahoo.com

Multilingual entrepreneur with diverse experience and expertise in business strategy, healthcare, offshore technology and project management.

KEY ACCOMPLISHMENTS

- ▶ Improved healthcare standards for a 500 bed level II trauma center in the Chicago suburbs
- ▶ Execution of physician turnover reduction program leading to $5 million annualized savings for a Fortune 200 health benefits and insurance company.
- ▶ $1 million cost containment for biomedical manufacturing company
- ▶ Improved Marketing Claims for $100 million dollar product line for a Fortune 500 Biomedical company
- ▶ Developed one of the nation's largest wound care staffing solutions in Phoenix, AZ.

PROFESSIONAL EXPERIENCE

Windstone Capital Partners – Scottsdale, Arizona June 2005-present

Managing Director

Engaged in providing startup to mid-sizes companies institutional investments, mergers and acquisitions, advisory services and strategic solutions for business growth and development

Consultant - Phoenix, Arizona *July 2003- present*

Hyperbaric Medicine and Wound Care –*Clinical Director* and development responsibilities for 9 hospitals in the greater Phoenix Area including acute care, inpatient and outpatient services. Involved in clinical trials for advanced wound technology.
Emergency Medicine – Luke Air Force Base/ Spectrum Healthcare and Team Health/Banner Baywood Medical Center
Physician Review and Expert Witness – Performing case based review and expert opinion for PRN Medical, MCMC and MedExperts, Maximus and Viriginia Health System.
Business Strategist- Developing new markets and improving business growth for several medical and non-medical businesses with gross revenue between 500k and 5 million.
Speaker's Bureau- providing educational programs for Pfizer, HealthPoint, Johnson and Johnson and KCI and Bristol-Myers.

CIGNA Healthcare of Arizona Phoenix, Arizona *July 2001 – July 2003*

Adult Medicine Department Physician

- •Chairperson Tobacco Cessation Program
- •Chairperson for Physician Turnover Reduction
- •Involved in all aspects of chronic outpatient care including pediatrics and adult medicine
- •Urgent Care Physician
- •Physician Lead on Inpatient Case Management Optimization and Geriatric Preventative Care for Westridge Health Center
- •Committee Member on Staff Model Hospital Bed Day Reduction Program
- •Developed the hypertension protocol for 17 healthcare centers

Spray Technology, Inc Tempe, Arizona Jan 2003 – Feb 2004

Chief Executive Officer

•Key person in acquisition, management restructuring and product line development for the second largest commercial spray equipment retail and repair center in Arizona.

•Improved profit margins by 30% and gross revenues by 25% within one year and subsequently sold to newly hired management.

Arizona College of Osteopathic Medicine Glendale, Arizona July 2001 – present

Adjunct Associate Clinical Professor

•Teaching Medical Students Primary Clinical medicine

Emergency Physician Associates Effingham, Illinois April 2001– July 2001

Emergency Physician – Temporary - Part-time Physician managing a 20,000 plus volume Emergency room

Emergency Consultants Inc. (ECI) Michigan & Indiana Sept 2000 – June 2001

Limited Partner Emergency Physician – Part time Physician managing 12,000 volume Emergency room

Midwest Medical Management Indianapolis, Indiana Jan 2000 – June 2001

Emergency Physician- Part-Time Physician managing a 10,000-volume emergency room

Northwestern University Chicago, Illinois *June 1995-Apr 1996*

Research Associate for the department of Otolaryngology

•Design and development of a physical model simulating the vocal tract

Becton Dickinson Company Franklin Lakes, N.J. *July 1992-Aug 1993*

B-D Division - Supervisor

•Responsible for all aspects of production of 3 cc and 1 cc hypodermic syringes.

Ivers-Lee Division - Production Coordinator

•Development of *High Performance Work Teams* throughout the production facility.

•Group leader - Cost / Waste Reduction Program for drug packaging.

VACUTAINER Systems Division, - R&D Engineer

•Performed statistical analysis to substantiate an improved sharpness claim for blood collection needles.

•Revised product designs to improve tolerances and meet specifications for plastic components.

Ramblax and Company Union City, NJ Aug 1993 – Jan 1998

Senior Project Manager

•Obtained venture funding for a start-up wireless communications company-Verma Labs.

•Formulated and executed a business strategy to leverage U.S. contracts for an Indian based software company- Silverline which eventually became the fifth largest software maker in India.

•Negotiated proprietary pharmaceutical technology transfer for a pharmaceutical company in Latin America.

Jet Propulsion Laboratory / NASA Pasadena, California *May 1990-Dec 1990*

Systems Analyst for the Advanced Propulsion Technology Group.

•Optimized a heat transfer model for a Liquid Plume Experiment.

•Low Earth Orbit decay, trajectory and radiation effect analysis for nuclear propulsion spacecraft.

•Developed a Liquid Propellant Resupply Dynamic Model for the U.S. Army.

POST-GRADUATE TRAINING

MacNeal Health Network / Rush Medical Chicago, Illinois Jan 1999-June 2001

Family Practice Resident

•Family Practice Quality Assurance Committee- Reviewing charts to assess patient management and develop guidelines and protocols to improve patient care. Assisted in the design of the Pneumonia Admission Protocol.

•Assisted in the development and redesign of the Family Practice Web Site

•Co-developer of the Intensive Care Manual

Resurrection Hospital Chicago, Illinois June 1998- Jan 1999

Emergency Medicine Resident

Managed patients in the critical care and trauma settings.

Transferred to Family Practice to obtain experience in longitudinal patient care.

EDUCATION

Midwestern University/CCOM Downers Grove, IL. Aug 1994- Jun 1998

Doctor of Osteopathy with Honors

Rensselaer Polytechnic Institute Troy, NY Aug 1988-May 1992

B.S. Aeronautical Engineering

Dean's List - 1988-1992

Licensure Examinations/ Arizona State Licensed Physician
Board Certified American Board of Family Practice (ABFP)

Certifications Board Certified in Wound Management (AAWM)
Hyperbaric Medicine Team Training
Pediatric Advanced Life Support Certified
Neonatal Resuscitation Certified
Advanced Cardiac Life Support Certified
Advanced Trauma Life Support Certified

RESEARCH/PUBLICATIONS

- Bohringer Ingelheim speaker on Hypertension and Stroke Prevention
- Principal Investigator –Developing guidelines and recommendations for "safe age" infant air travel.
- Principal Investigator – Bioengineered Skin Substitute for Pressure Ulcers- Novartis
- "Piriformis Syndrome." Internet Web Site- www.emedicine.com (sports medicine)
- "Brachial Plexus Injury in the Newborn." Ambulatory Care Conference. MacNeal Hospital Jan 2000.
- "*Pediatric Air Travel*" presentation at the American Academy of Family Physicians Scientific Assembly and North American Primary Care Research Group
- "A Study of Various Lubricants and Freon Free Lubricant Solvents for Blood Collection Needles" - Becton-Dickinson internal study
- "Nuclear Orbit Decay Study for Low Earth Orbit Satellites" - internal study at NASA/JPL - not released for the public.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:	)	
	)	Before the Examiner
Garret D. Cawthon	)	Marina Lamm
	)	
Serial No. 10/626,069	)	
	)	Group Art Unit 1616
Filed July 24, 2003	)	
	)	
METHODS COMPOSITIONS AND SYSTEMS FOR THE PREVENTION AND TREATMENT OF DIAPER RASH	)	

DECLARATION OF DEAN O. HARPER UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dean O. Harper, hereby declare that:

1. I have carefully reviewed the above-captioned patent application and I am familiar with its content.

2. My degrees include a B.S.Ch.E. degree in Chemical Engineering from Purdue University, a M.S. degree in Physical Chemistry from Purdue, and a PhD. In Chemical Engineering from the University of Cincinnati. I have taught Chemical Engineering at both West Virginia University (six years) and the University of Louisville (34 years), and have significant experience in research relating to transport phenomena and polymer engineering. Further information relating to my education and experience in this field is provided in my *curriculum vitae*, a copy of which is attached hereto as Exhibit A.

3. I have carefully reviewed the outstanding Office Action in the present case, dated November 30, 2005, and the art references cited therein, together with the prior Office Actions dated June 16, 2005 and November 26, 2004. I have also considered the current amendments to claims 39, 51, 58 and 59, and new claims 74-79 that are set forth in the document entitled "Response to Office Action" to which the present Declaration is attached and the Declarations of Dean Harper and Garret Cawthon that are submitted herewith. It is my opinion, for the reasons discussed herein, that it would not be obvious to a person of ordinary skill in the art to make a non-aerosol spray-on, run-off resistance product by simply adding ingredients from one formulation into another formulation or diluting a viscous paste/ointment with a solvent. More complex behavior is needed to make a liquid that is sprayable using non-aerosol mechanisms, i.e., without the use of propellant gases entrained therein, and that does not run off of the skin treatment area. The two goals have conflicting properties. For example, the viscosity must be thin enough to allow spraying but thick enough to prevent run-off. Dr. Cawthon's formulations offer unique viscosity performance in that they thin under shear, then thicken after the shear is removed, creating the desired outcome. Moreover, the yield stress often observed helps reduce run-off.

4. The study of the deformation and flow of matter – gases, liquids, and solids - is known as rheology. With reference to claim 1 of the present patent application, the claimed invention involves formulations that consist of two major phases, a *continuous phase* ("a fluid base material comprising a member selected from the group consisting of mineral oil, silicone oil, an organic solvent, plant-based oil, water, and mixtures thereof") and a *discontinuous phase* ("a member selected from the group consisting of a solid particulate material, lanolin, petrolatum, cod liver oil, calendula, chamomile, paraffin wax, microcrystalline wax, and mixtures thereof"). Selection of the continuous phase has a significant impact on the overall rheology of the mixture. The selection of the discontinuous phase, and its concentration, can greatly modify the rheology of the continuous phase. This is due to the interactions between the two (or more) components. Moreover, volatile solvents in the continuous phase can provide a composition that creates more viscous coating on the skin's surface after spraying due to the evaporation of the solvents.

5. When I read the references to which the outstanding Office Action referred in support of claim rejections, I observed the following:

(1) Of all of the references of record in this case, I believe that only Adams et al., Mulder, Gebhart and Huffstutler make any mention of embodiments that are described as being sprayable. The remaining references teach nothing about compositions having physical properties of a composition that would be necessary for the composition to be sprayable, which is critical to the operation of the present invention.

(2) of the references that describe embodiments as being sprayable, those described in Adams et al., Gebhart and Huffstutler are all delivered using "aerosol" systems that use propellant gases. An aerosol is "a gaseous suspension of ultramicroscopic particles of a liquid or a solid" (McGraw-Hill Dictionary of Scientific and Technical Terms (1978) 2nd ed., p.34).

The invention claimed in the present application by Dr. Cawthon is significantly different than the composition described in Adams, Gebhart & Huffstetler because it does not have propellant gases entrained therein. In a propellant-based spray formulation, the propellant helps dilute the formulation in a fluid (the gas) so that a thicker, more viscous, composition once entrained in a gas, can be sprayed. In addition, the elevated pressure of the propellant helps push the materials through the actuator, which also allows for compositions of higher viscosity to be sprayed through a nozzle. In these references, propellants are key in achieving spray-ability. In contrast, the invention described and claimed by Dr. Cawthon in the present application involves compositions having physical properties that provide good sprayability and also good resistance to run-off after being sprayed, all without the use of propellant gases entrained therein.

6. Of all of the reference cited in the present case, only Mulder purports to describe a composition that is sprayable, but is silent as to the use of propellant gases (See Table 1 at Column 5 of Mulder). The description in the Mulder reference of the composition set forth in Table 1, however, also suggests that this composition would not

be able to form a coating that "does not run off of the skin treatment area," as recited in Dr. Cawthon's pending claims. Specifically, Mulder states that:

> The mechanical action of the spray liquid permits a complete flushing of the wound site to soften and rinse away debris from the wound. (Mulder, Column 5, line 65 to Column 6, line 1).

In view of the suggestions of sprayability and run-off after spraying that would be required to provide the "rinsing" function discussed above, a person of ordinary skill in the art would not expect this composition to have the properties claimed in the present application (i.e., sprayability and run-off resistance). Moreover, upon considering the list of ingredients set forth at Column 5 in Table 1 of Mulder, a person skilled in the art might expect that the composition would not be sprayable at all absent propellant gases entrained therein. Indeed, Dr. Cawthon's declaration, which is submitted herewith, sets forth the results of experimental testing of the composition described in Table 1 of Mulder, showing that this composition in fact does not have the properties described and claimed in the present patent application.

7. With the above in mind, it is clear that the references cited in the outstanding Action lack teachings or descriptions that are fundamental to the present invention. I therefore turn my attention to what a person of ordinary skill in the art would or would not have been motivated to do based upon the more general concepts contained in these references. I submit based upon my experience that a person of ordinary skill in the art would not have been motivated by any reference of record to prepare a diaper rash treatment composition that is sprayable without the use of entrained propellant gases and that has rheological properties suitable to prevent run-off after being sprayed onto a skin treatment area because he or she would have no reasonable expectation of success due to the highly complex, and seemingly inconsistent, rheological properties that would be required to achieve this functionality. As one knowledgeable in the complex behavior of liquids (single-phase and multi-phase) and slurries, I can attest to the fact that a formulation having the diverse rheological

properties that would be necessary to achieve the performance described and claimed in the present application would not have been envisioned by a person of ordinary skill in the art in view of the references of record in this case.

8. For purposes of discussing the complex rheological nature of the compositions having the properties of sprayability and run-off resistance described and claimed in the present application, the following discussion addresses the issues of (i) rheological characterization, (ii) delivery, and (iii) application of the complex fluid-solid systems – slurries under consideration. By "characterization" I mean the qualitative and quantitative description of the slurries that would permit the engineering design of the delivery system for the product. By "delivery" I mean the atomizing transfer of the product from its container to the surface to be treated. By "application" I mean the product's behavior on the treated surface after delivery; the characterizing equation should permit a prediction that could be confirmed by demonstration.

9. As desirable as it would be to "characterize" the rheology of the contemplated compositions by designing a model that provides a qualitative (i.e., equation) and quantitative (i.e., the numerical values of the parameters in the equation) description of the slurries that would permit the engineering design of the delivery system for the product, this is unrealistic in reality. In all of my teaching – 40 years as a professor of chemical engineering – such modeling was an ideal that has not been attained to my knowledge. Rather, set forth below is information that relates, in general, to fluid characterization, the forces that influence a fluid's behavior, and the equations – in name only – that have been found to be capable of accomplishing the above "ideal".

10. Fluids (gases and liquids) respond to applied forces in a manner that is a function of (i) their properties [see Table 1] and (ii) the nature of those forces [see Table 2]. Generally, the fluid is given a name that depends upon the associated characteristics [see Table 3]. These topics are addressed separately below.

11. The properties of a fluid can be described using the terms set forth in Table 1 below. Also included in the table are non-property influences on the rheology of a fluid. The use of "versus", -v.-, in Table 1indicates a dichotomy; the property **must** be in one or the other category. Abbreviations will be used in subsequent tables.

Table 1
The Properties of Fluids.

Property	Characteristic	Qualifier
Density: DENS	Incompressible (INCP)	-density is a constant
	-v.-	
	Compressible (COMP)	-density is variable
Viscosity: VSTY	Invisid (INVS)	-viscosity is zero
	-v.-	
	Viscous (VISC)	-viscosity is finite and non-zero
Initial Yield Stress: INYS	Non-Plastic (NNPL)	-INYS is zero
	-v.-	
	Plastic (PLAS)	-INYS is finite and non-zero
Shear Rate: SHRT	Independent (SRIN)	-viscosity is not a function of the rate at which the fluid is sheared
	-v.-	
	Dependent (SRDE)	-viscosity is a function of the rate at which the fluid is sheared
Elasticity: ELTY	Inelastic (INEL)	-upon release of an applied force, the fluid does not respond; i.e., it no longer deforms
	-v.-	
	Elastic (ELAS)	-upon release of an applied force, the fluid responds by continuing to deform for some time (see visco-elastic behavior below)
	Non-Property Influences	
Time: TIME	Time-Independent (TMIN)	-fluid behavior is not a function of the duration of the applied forces
	-v.-	
	Time-Dependent (TMDE)	-fluid behavior is a function of the duration of the applied forces
Temperature: TEMP		-Almost all fluid properties are a function of temperature

12. A significant aspect of rheology that bears on the present discussion is the response of the fluid to various types of applied force. There are four characteristics of applied forces that influence the responses of materials, including fluids: (i) the type of force, (ii) the magnitude of that force, (iii) the duration, in time, that the force is applied, and (iv) the rate at which the force is applied. Table 2 details these influences.

Table 2
Classification of Applied Forces.

Type of Force:

Tension – co-linear forces directed away from each other

Compression – co-linear forces directed toward each other

Shear – non-co-linear forces directed away from each other

Torsion – non-aligned rotational forces directed away from each other

Magnitude of Force: Low-to-High

Duration of Application: Short-to-Long

Rate of Application: Slow-to-Fast

The visco-elastic liquid "Silly Putty" – poly(dimethylsiloxane) – serves as an excellent prototype to illustrate these influences. To demonstrate that material's responses to the following combinations of force characteristics, one starts with the given shape.

"Cigar":	High Tension, Short and Fast -brittle failure Low Tension, Long and Slow -ductile failure; "pure" viscous response
Ball:	High Compression, Short and Fast -droplet formation Low Compression, Short and Fast –bouncing; "pure" elastic response Low Compression (under its own weight), Long and Slow -formation of a disk-like "puddle"
Cube:	High or Low Shear, Short or Long, Fast or Slow -liquid-like responses

A set of descriptive characteristics for visco-elastic (VE) behavior is (i) instantaneous strain (IS) [a spring] or (ii) retarded strain (RS) [a dashpot, i.e., a close-fitting piston inside a cylinder], and (iii) complete recoverability (CR) or (iv) incomplete recoverability (IR).

VE + CR = a visco-elastic solid (VES); VE + IR = a visco-elastic liquid (VEL).

In response to the sequence "force applied + elapsed time + force released", combinations of springs and dashpots have been given the following names:

A spring & dashpot in series – Maxwell VEL (IS+RS;IR)

A spring & dashpot in parallel – Voigt/Kelvin VES (RS;CR)

Voigt/Kelvin VES & spring in series – Zenner VES (IS+RS;CR)

Voigt/Kelvin VES & dashpot in series – Jeffreys VEL (RS;IR)

Voigt/Kelvin VES & Maxwell VEL in series – Burgers VEL(IS+RS;IR)

"Silly Putty" behaves as a Burgers VEL.

13. The complex responses of various fluids to a variety of forces have been given the names shown in Table 3. This list is in no-way a complete and exhaustive one (for other named-fluids see Harper[1]).

Table 3
Classification of Fluids

Prop.	Char.	Fluid Name:	**Ideal**	**Navier-Stokes**	**Newtonian**	**Non-Newt.**	**Bingham**	**Shear Thin.**[2]	**Shear Thick.**[3]	**Brodkey**[4,5]
DENS										
	INCP		✔	✔	✔	✔	✔	✔	✔	✔
	COMP				or ✔					
VSTY										
	INVS		✔							
	VISC			✔	✔	✔	✔	✔	✔	✔
INYS										
	NNPL		✔	✔	✔	✔		✔	✔	✔
	PLAS						✔			
SHRT										
	SRIN		✔	✔	✔		✔			
	SRDE					✔		✔↓[2]	✔↑[3]	✔↓↑[4]
ELTY										
	INEL		✔	✔	✔	✔	✔	✔	✔	✔
	ELAS	(see visco-elastic classifications above)								
TIME										
	TMIN		✔	✔	✔	✔	✔	✔	✔	(✔)[4]
	TMDE									✔

(Table 3, cont.)

TEMP

The viscosity of non-polymeric fluids decreases with increasing temperature. Polymeric fluids exhibit three regions of behavior as a function of temperature: T < Tg, brittle solid; Tg < T < Tm, flexible solid; Tm < T, mobile liquid. Tg is the glass transition temperature; Tm is the melting temperature.

Footnotes to Table 3

[1] Harper, D.O., "Plastic Parts Processing II", *Handbook of Materials Selection* (2002) Myer Kutz, Ed., John Wiley & Sons, New York NY; pp.993-1036. This chapter is primarily concerned with the polymers used to make "plastic parts". In shear flows, they inherently exhibit First and Second Normal Stress Functions, in addition to shear viscosity. Since polymer processing also may involve extensional flows, their rheological characterization also requires measurement, and modeling, of one or more of the extensional viscosities: Uniaxial, Planar, or Biaxial.

[2] Shear-thinning fluids are usually called "pseudo-plastic". Their viscosity decreases with increases in shear rate.

[3] Shear-thickening fluids are usually called "dilatant". Their viscosity increases with increases in shear rate.

[4] Harper, *loc. cit.*, pp.1002-4. Though seldom used, the Brodkey model is, to my knowledge, the only one that permits characterizing time-dependent as well as time-independent non-plastic fluids. It inherently includes the well-known and often observed behaviors of "low-shear-rate limiting viscosity" and "high-shear-rate limiting viscosity". One feature that may discourage its application is that it is explicit in shear **stress**, rather than shear **rate**.

Although R.S.Brodkey, and his co-worker D.A.Denny, did not extend their model to include plastic fluids, that could bereadily accomplished. In addition, each of the model's nine parameters could be determined to be temperature dependent, creating a horrendously complex, but very powerful, equation.

[5] Brodkey, R.S., *The Phenomena of Fluid Motions* (1967) Addison-Wesley, Reading MA; pp.393-6.

14. To comment briefly on instrumentation, the instruments that are commonly used to measure viscosity are made by Brookfield™ (rotational) and Instron™ (capillary). The former can never characterize a non-Newtonian fluid. This is because their spindle, or cup-and-spindle, arrangements subject the fluid to a range of shear rates, and the viscosities of non-Newtonian fluids are explicitly functions of shear rate. Those researchers who claim to do so fool themselves by

assuming a non-Newtonian model for the fluid and use the data to determine the parameters in that model. There is no way to ascertain if the model assumed is actually applicable. An additional limitation is the inability of a Brookfield to measure First or Second Normal Stress Functions. To determine these one needs to use a rheometer such as those made by Rheometrics™. Capillary viscometers, on the other hand, can characterize a non-Newtonian fluid. Although they inherently subject the fluid to a range of shear rates, from zero at the center-line of the capillary to a maximum at the stationary wall, the well-defined and uniform geometry permits interpretation of the data to obtain a unique viscosity at a given shear rate; the data reduction requires the use of a transformation. The measurement of the dimensions of the extrudate from a capillary viscometer to determine the Normal Stress Functions is fraught with difficulties, but researchers have reported such data. Neither a rotational nor a capillary viscometer can characterize a time-dependent material. This must be done with a Dynamic Mechanical Spectrometer. TA™ Instruments makes such a machine.

15. Based upon a careful review of the compositions described and claimed in Dr. Cawthon's present patent application and the use of the non-propellant-based delivery systems described and claimed therein, it is my opinion based upon my significant experience in this field that the compositions described and claimed therein that I have studied exhibit "time-dependent, shear-thinning, plastic" rheology. I will now address each of these items, but in reverse order.

16. With respect to plasticity, what I mean is that the composition when shaken, may be poured out of the bottle with its cap off; however, it cannot be dispersed through its intended path – the nozzle – unless a force is applied to the plunger. This may not meet the precise meaning of "initial yield stress" to a rheologist, but as a pragmatic engineer I attest to the fact that an initial stress must be applied to cause the material to move. This force does more than simply move the slurry through its conduit; it must also create the sizable new surface area of the resultant droplets. If too slight a force is used, one simply obtains a drool; sufficient force must be applied to accomplish atomization of the product. (Compare the behavior I describe when a ball of silly putty is subjected to compression in paragraph 12 above).

17. With regard to shear-thinning, the viscosity of the product in its container, before shaking, exhibits – to the eye – a "high" viscosity. Not as high as a commercial pancake syrup or molasses, but clearly one that is greater than that of water. Upon shaking, the viscosity is lowered somewhat (see the discussion on "thixotropy" in paragraph 19 below). Then, as the slurry flows through the small tube inside the bottle, it experiences a very high shear rate, especially as a result of the aforementioned "high" force that must be applied. The fact that one is able to accomplish this feat, as well as atomization, is convincing evidence that the mixture is rheologically "shear-thinning", not shear-thickening. That is, the viscosity of the composition is reduced by the action of being sheared in the small diameter riser. (If it were shear-thickening, the resistance to flow would increase as the applied force was increased. Also, the assertion that the slurry could not be Newtonian, and hence be shear-rate independent, is based on extensive prior knowledge of similar mixtures.)

18. With regard to time-dependency, this term, as described in Table 1, addresses that fact that the rheological response of a material is a function of the duration of the applied force. Such behavior has been well known and manifested in such slurries as mayonnaise and household paints. Each of these common materials has a high viscosity when un-sheared, but that viscosity is greatly reduced upon the action of shear. As for mayonnaise, a customary use is to take the "gloppy" food from the jar on a knife and spread it on bread. That action is one of shearing at a fairly low rate, but the viscosity is lowered. On the other hand, if one does something quite unusual for mayonnaise - namely put it in a blender – high shear rates lower the viscosity sufficiently to make this food a pourable liquid! The time dependency of viscosity may be demonstrated by varying the length of time that it is sheared. And, more convincingly, when one lets the mayonnaise set un-sheared, this mobile liquid returns to its "gloppy" state. In other words, the phenomenon is physical, not chemical; the change in its fluidity is reversible.

19. The other common material that exhibits this behavior is a latex paint, which is even labeled as being rheologically "thixotropic", the technical term for this time-dependent reversible performance. Quoting from the American Heritage Dictionary, "thixotropy, n. The property exhibited by certain gels of becoming fluid when stirred or shaken and returning to the

semisolid state upon standing." In paints, the product is un-sheared in the can, and hence has a relatively high viscosity. When one dips a brush into the slurry, the bristles take up some paint; and, when one lifts the brush out of the can, the paint does not drip – it hasn't received enough shearing in that action to significantly lower its viscosity. But, when one shears the paint by brushing it on a substrate, the paint readily flows onto that surface. Surprisingly, to the layman, after the brush is removed from the surface, the paint does not "run" – that is, if the proper painting practice is followed. The same results occur if one used a roller to apply the paint. In the pan, the viscosity is "high". Rolling shears the paint enough to fill the spaces between the roller's fibers. Rolling the paint on a surface thins it enough to provide flow-ability. As the paint can's label says, "When painting an overhead surface such as a ceiling, always begin on an as yet unpainted area and work toward the previously painted section." This "proper practice" is necessary to give the thixotropic behavior time to occur – namely, time for the structure to rebuild and prevent dripping.

20. The compositions described and claimed in the present patent application exhibit these properties: high viscosity in the absence of shear (i.e., "unshaken"); lower viscosity upon application of shear (i.e., upon shaking); even lower viscosity upon discharge; atomization; coverage of the affected surface; and structure build-up, preventing "run-off". The high viscosity inside the bottle helps suspends any particulate solids and insoluble materials to inhibit settling; the shear thinning behavior within the actuator helps with atomization; the high viscosity which is developed on the skin's surface helps prevent run-off and rub-off of the skin.

21. For the reasons set forth herein, I believe that the references of record in this case do not include sufficient information to enable anyone to prepare a diaper rash treatment composition that is sprayable without the use of propellant gases entrained therein, and that has rheological properties suitable to prevent run-off upon being sprayed onto a skin treatment area. In particular, the references of record provide no reasonable expectation of success due to the highly complex, and seemingly inconsistent, rheological properties that would be required to achieve this functionality.

22. I further declare that all statements made herein are of my own knowledge, are true and that all statements made on information and belief are believed to be true; and further

that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

23 May 2006
Date

Dean Owen Harper
Dean O. Harper, Ph.D.

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EXHIBIT A

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Experience

Dec. 1999 – May 2000 Acting Chair, Department of Chemical Engineering

1982–6/30/2003 Professor, Chemical Engrg.

1969-1982 Assoc. Professor, Chemical Engrg.

Dept. Chemical Engrg., Univ. of Louisville

- Taught undergraduate and graduate courses, lecture and laboratories.
- Directed 100+ M.Engrg., M.S., and Ph.D. theses or dissertations.
- Served on Faculty Senate and Univ. Committees.
- Served on Speed Scientific School Faculty Council (Pres. twice) and Unit Committees.
- Served as Acting Chair (six months) and on Deptl. Committees.
- P.E. #9375 KY (Chemical)
- Expert witness for the City of Louisville and numerous Attorneys at Law.
- Consultant to several Louisville chemical companies.
- Part-time employment and partial Sabbatical at G.E. Appliance Park

1963–1969 Asst. Professor, Chemical Engrg.

Dept. Chemical Engrg., West Virginia Univ.

- Taught undergraduate and graduate courses, lecture and laboratories.
- Directed four M.S. theses.
- Served on Deptl. Committees.
- Elected to Omega Chi Epsilon.
- Part-time employment at U.S. Bureau of Mines.

1960–1962 Acting Instructor, Chemical Engrg.

Dept. Chemical Engrg., Univ. of Cincinnati

- Taught undergraduate lecture courses.

1959–1960 Teaching Fellow, Chemical Engrg.

Dept. Chemical Engrg., Univ. of Cincinnati

- Taught undergraduate laboratories.

1956–1957 Junior Engineer

Thiokol Chemical Corp., Huntsville AL

- Reduced and correlated data from solid-propellant rocket engine tests.
- Took four graduate level courses at the Univ. of Alabama, Huntsville Ext.

1953-1954 Instructor's Asst., Genl. Engrg.

Dept. of General Engrg. Purdue Univ.

- Instructor's Asst. in Descriptive Geometry

Education

1959–1963 Graduate student, Chemical Engrg.

Dept. of Chemical Engrg., Univ. of Cincinnati

- Earned Ph.D. [Chemical Engrg.] (August 1967).
- Awarded the Laws Fellowship.
- Elected to Phi Lambda Upsilon.

1957-1959 Graduate student, Physical Chemistry

Dept. of Chemistry, Purdue Univ.

- Earned M.S. [Physical Chemistry] (May 1959).
- Teaching Assistant, Physical Chemistry laboratory.

1952-1956 Undergraduate student, Chemical Engrg.

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Dean Owen Harper was born in Cincinnati OH, 01 December 1934, was educated in the public schools of Indianapolis IN from 1940-52, graduating from Arsenal Technical High Schools in June 1952. He earned the B.S.Ch.E. degree from Purdue University in June 1956, the M.S.(Physical Chemistry) from Purdue in May 1959, and the Ph.D.(Chemical Engineering) from the University of Cincinnati in June 1967.

In the period from July 1956 to August 1957, he was a Junior Engineer for the Thiokol Chemical Corporation, Redstone Arsenal, Huntsville AL. During this year he took four (4) graduate courses from the University of Alabama, Huntsville Extension.

In September 1963,he was appointed Assistant Professor of Chemical Engineering at West Virginia University, Morgantown WV, where he remained until June 1969. There he taught undergraduate and graduate courses and directed graduate research students in chemical engineering. He also worked part-time at the U.S. Bureau of Mines, Morgantown WV, during several summers and academic semesters.

From July to September 1969, Dr. Harper was a Research Polymer Engineer at the E.I. du Pont de Nemours & Co. Louisville Works. In October 1969, he was appointed Associate Professor of Chemical Engineering at the University of Louisville. In 1973, he was granted tenure there, and in 1982 was promoted to (Full) Professor. In December 1999, he was appointed Acting Chair of the Department of Chemical Engineering and served as such until a permanent chair was hired in June 2000. Upon his retirement on 30 June 2003, after 40 years of academic employment, he was awarded Professor Emeritus.

He has taught undergraduate and graduate courses in chemical engineering, physical chemistry, materials science and mathematics during this time. He has directed the research of more than 100 Master of Engineering, Master of Science, and Ph.D. students during his six years at West Virginia University and 34 years at the U. of L.

Dr. Harper has been a part-time employee of General Electric Appliance Park twice (the Summer of 1972 and the Spring of 1981), and a consultant to numerous companies in the Louisville area, including Brown & Williamson, General Electric, and Rohm and Haas of KY. He has also served as a consultant and/or expert witness for the U.S. Dept. of Justice, the City of Louisville, Louisville Gas & Electric, and numerous Attorneys at Law.